Irvine Scientific

January 27, 2000

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IRVINE SCIENTIFIC

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

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Contact: Roberta L. Johnson

Date Submitted: January 27, 2000

Device Identification:

Trade Name:	Blastocyst Freeze Media Kit Blastocyst Thaw Media Kit
Common Name:	Blastocyst cryopreservation media Blastocyst thawing and recovery media
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Description:

The four media that comprise the two kits, Blastocyst Freeze Media Kit and Blastocyst Thaw Media Kit are all based upon the formulation of modified human tubal fluid (K983586). The two media in the Blastocyst Freeze Media kit

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are intended to be used sequentially, for the preparation for, and cryopreservation of, human blastocysts. The first medium to be used, F1, which is used in preparation for freezing, contains 5% glycerol. The second medium, F2, to be used during cryostorage, contains 9% glycerol and 0.2M sucrose. Both F1 and F2 are also supplemented with human serum albumin (HSA).

The two media in the Blastocyst Thaw Media kit are also intended for sequential use in the thawing and recovery of cryopreserved human blastocysts. The first medium used in the thawing process, T1, contains 0.5M sucrose. The second medium, T2 contains 0.2M sucrose. Both T1 and T2 contain HSA. All four media contain gentamicin.

Intended Use:

The Blastocyst Freeze Media Kit is intended for use in the preparation for, and cryopreservation of, human blastocysts. The Blastocyst Thaw Media Kit is intended for use in the thawing and recovery of cryopreserved human blastocysts.

Technological Characteristics:

Blastocysts are routinely stored for use in future assisted reproductive procedures. In some instances, excess eggs will be retrieved from the patient, and fertilized. If development of these fertilized eggs indicates a potential for viability during implantation, they may be frozen for future use. In the event that the current transfer is unsuccessful, and does not result in a clinical pregnancy, the patient has embryos in reserve that may be used for implantation in future procedures. Blastocysts are also routinely frozen when patients have a history of unsuccessful implantation procedures, and also for those patients who desire multiple children. Media to protect the blastocysts during the preparation for cryopreservation, during storage, and ultimate thawing and recovery are, therefore, different in composition from media used for gamete retrieval, during fertilization and implantation.

The media in the Blastocyst Freeze Media Kit, F1 and F2 are designed to be used sequentially for the preparation of blastocysts for cryopreservation, and as the protective media during cryostorage. The media in the Blastocyst Thaw Kit, T1 and T2 are also designed for sequential use, in the thawing and recovery of cryopreserved human blastocysts. None of the media are intended to contact the patient.

Performance Data:

The Blastocyst Freeze Media Kit and the Blastocyst Thaw Media kit have been studied by five independent field laboratories, using mouse blastocysts and the protocol for blastocyst freezing, thawing and recovery presented in the product inserts for these kits. The conclusion from all laboratories that evaluated the kits was that the Blastocyst Freeze Media kit and Blastocyst Thaw Media kit performed at least as well as the control freeze/thaw media in use in the laboratories.

Additional Information:

Endotoxin, mouse blastocyst freezing and recovery assay performance and sterility tests will be performed as a condition of release for these products. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

Conclusion:

The results from the field testing of these products demonstrates that Blastocyst Freeze Media Kit and Blastocyst Thaw Media kit are suitable for their intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

PROPOSED LABELING

Three copies of the proposed labeling for Blastocyst Freeze Media Kit and Blastocyst Thaw Media Kit are enclosed with this submission, beginning on the following page. These labels include vial labels, kit labels, and the proposed product insert. Some information, such as results of endotoxin tests, will be included in the lot-specific certificate of analysis provided with the product. An example of the format for these certificates of analysis, and of the information supplied in them, may be found in Appendix B to this submission. Some required information, such as pass/fail specifications for the endotoxin and blastocyst recovery assays are not included on the vial labels due to space constraints. Such information will be included on the kit label. Please note that individual vials of the media are not offered for sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Ms. Roberta L. Johnson
Manager, Regulatory Affairs
IRVINE SCIENTIFIC
2511 Daimler Street
Santa Ana, CA 92705-5588

Re: K000309
Blastocyst Freeze Media Kit, F1 and F2, and
Blastocyst Thaw Media Kit, T1 and T2
Dated: January 27, 2000
Received: February 1, 2000
Regulatory Class: II
21 CFR§884.6180/Procode: 85 MQL

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K000309

Device Name: Blastocyst Freeze Media Kit; Blastocyst Thaw Media Kit

Indications for Use:

Blastocyst Freeze Media Kit is intended for use in the assisted reproductive procedure, blastocyst cryopreservation. The two media kit is designed to protect human blastocysts during rapid freezing procedures and during frozen storage.

Blastocyst Thaw Media Kit is intended for use in the assisted reproductive procedure of thawing frozen blastocysts. The two media kit is designed to protect human blastocysts during warming and thawing after cryopreservation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000309